

## **REMARKS**

### ***Status of claims***

Claims 1-30 are pending.

### ***Claims rejections: Obviousness-type double patenting***

The Examiner rejected claims 1, 2, and 11-16 on the ground of nonstatutory obviousness-type double patenting as unpatentable over claims 11, 12, and 14-16 of U.S. Patent No. 7,044,975 (hereafter "the '975 patent") in view of U.S. Pat. No. 5,047,060 to Henssge (hereafter "Henssge").

Among other differences, claim 1 of the present application requires that the stem member's shaft include a midshaft portion, at least a portion of which is so tapered that the cross-sectional area of the shaft in that portion continuously decreases distally. This feature offers nonobvious advantages over the subject matter claimed in the '975 patent when combined with other features that claim 1 requires.

While tapered stems typically may be seated more firmly in bone compared to cylindrical stems, they have a severe disadvantage: the exact seating depth is difficult to control. A cavity is prepared in the long bone into which the stem is to be inserted using a series of broaches. This series of broaches creates a tapering hole that approximates the shape of the tapered stem. The hole and the stem do not have (and cannot have, whatever the surgeon's skill) exactly complementary shapes, so the exact resting depth of the stem cannot be controlled. Moreover, the stem is forcibly inserted into the hole for a snug fit, and it is well known in the art that normal engineering tolerances in the manufacturing of a taper make it impossible to predict exactly how deeply a tapered stem will seat in a

manufactured tapered hole, let alone a hole created in bone with hand tools. Finally, the seating depth will also be affected by the particular properties of the patient's femur, including density and stiffness of the bone tissue, which can vary widely between individuals. Because the depth of the stem cannot be precisely controlled, the prosthesis may end up being too long or too short, thereby impairing the subject's anatomy. Even half an inch of leg-length discrepancy causes gait problems that require medical intervention.

But the presently claimed combination of a tapered stem with modular head and body members allows the user to select specific head and/or body members with dimensions that compensate for whatever depth at which the stem seats. And the friction-tight press fit between parts having constant cross-sectional geometries allows assembly to a very precise length, thereby facilitating the compensation to a high degree of accuracy.

The specific addition of a tapered stem thus adds a significant benefit that Applicants did not appreciate at the time the '975 patent's application was filed.

The Examiner also provisionally rejected claims 1 and 11-13 on the ground of nonstatutory obviousness-type double patenting as unpatentable over claims 1, 2, 3, 10, and 4, respectively, of Application No. 10/605,322.

Applicants ask the Examiner to reconsider and withdraw the rejection because Application No. 10/605,322 is no longer pending. It issued on May 16, 2006 as U.S. Pat. No. 7,044,975, the patent cited above in the obviousness-type double patenting rejection.

***Claim rejections: 35 U.S.C. § 102***

The Examiner rejected claims 1, 2, 8, 23, 24, and 26-28 under 35 U.S.C. § 102(b) as reciting subject matter anticipated by U.S. Pat. No. 5,032,130 to Schelhas (“Schelhas”). Applicants ask the Examiner to reconsider and reverse the rejection because Schelhas does not disclose every element recited in the rejected claims.

For example, Schelhas fails to teach the “constant cross-sectional geometry” limitations in claim 1. All claims require that: a) the spigot have a “locking band with a constant cross-sectional geometry along its length,” and b) the receiving portion have “a constant cross-sectional geometry along its length.” Although the Examiner took the position that Schelhas’s element 4 meets the required locking band with a constant cross-section geometry, Schelhas clearly shows in Fig. 2 and states at col. 3, lines 54-55 that element 4 constitutes *screw threads* on cylindrical pin 6. Similarly, Schelhas’s element 22 simply represents screw threads formed in clamping sleeve 20. Because a screw thread spirals along the length of a threaded component, the component necessarily has a varying cross-sectional geometry along its length. Thus Schelhas fails to teach either “constant cross-sectional geometry” limitation of claim 1.

Schelhas also fails to teach the “friction-tight press-fit” limitation of applicant’s claim 1. All claims require that “the spigot engages the receiving portion by friction-tight press-fit.” The Examiner cited Schelhas’s col. 2, line 55 to col. 3, line 4 as disclosing this limitation. But the claim requires that the *locking band* engage the receiving portion by friction-tight-press-fit. The passage the Examiner cited refers to a press fit between the sloping contact surfaces 8, 18, not a press fit between elements 4 and 22. Indeed, a press

fit between elements 4 and 22 is impossible because they have screw threads; they thus cannot be engaged by a press-fit; rather, they are engaged by twisting one into the other. And even if the Examiner likened a sloping contact surface 8 to the recited locking band, the sloping contact surface by definition lacks the required constant cross-sectional geometry along its length. Indeed, Schelhas nowhere shows a locking band having a constant cross-sectional geometry along its length that engages a receptacle by friction-tight-press-fit. Thus Schelhas fails to teach the “friction-tight press-fit” limitation of claim 1.

***Claim rejections: 35 U.S.C. § 103(a)***

The Examiner rejected claims 3-7 as reciting subject matter unpatentable over Schelhas in view of U.S. Pat. No. 4,908,032 to Keller; claims 9, 10, 25, 29, and 30 as unpatentable over Schelhas in view of U.S. Pat. No. 4,608,055 to Morrey et al. (or alternatively as unpatentable over Schelhas in view of Keller, further in view of Morrey); claims 11-16 as unpatentable over Schelhas in view of U.S. Pat. No. 4,963,155 to Lazzeri et al.; and claims 17-22 as unpatentable over Schelhas in view of U.S. Pat. No. 5,653,765 to McTighe et al.

Applicants ask the Examiner to reconsider and withdraw these rejections because none of the cited secondary references supplies the limitations of claim 1 that Schelhas lacks. In particular, none of these references teaches a spigot that includes “a locking band with a constant cross-sectional geometry along its length,” a stem bore that includes “a receiving portion with a constant cross-sectional geometry along its length,” and the requirement that “the spigot engages the receiving portion by friction-tight press-fit.”

For the reasons given above, Applicants ask the Examiner to reconsider and withdraw all rejections.

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Respectfully submitted,

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